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(54) **Ambulatory patient monitoring systems.**

(57) An ambulatory patient monitoring system (100) is provided for measuring and storing predetermined diagnostic parameters of a patient. The monitoring system includes a personal type computer (120) which may be selectively coupled to the portable portion (102) of system (100). Portable portion (102) may include one or more monitoring modules, such as ECG monitoring unit (110) and blood pressure monitoring unit (210). When ECG monitoring unit (110) and blood pressure monitoring unit (210) are disposed in side-by-side relationship and with respective optical interfaces (50, 254) in optical alignment, the two units operate in concert. ECG monitoring unit (110) supplies an R-wave gating signal to blood pressure monitoring unit (210) for establishing a window in which the receipt of a Korotkoff sound is expected. Additionally, the ECG unit (110) may trigger the blood pressure unit (210) to take a reading responsive to unit (110) identifying a predetermined abnormality in the ECG signal. Alternately, ECG monitoring unit (110) and blood pressure monitoring unit (210) may be used independently of one another as separate monitoring devices.

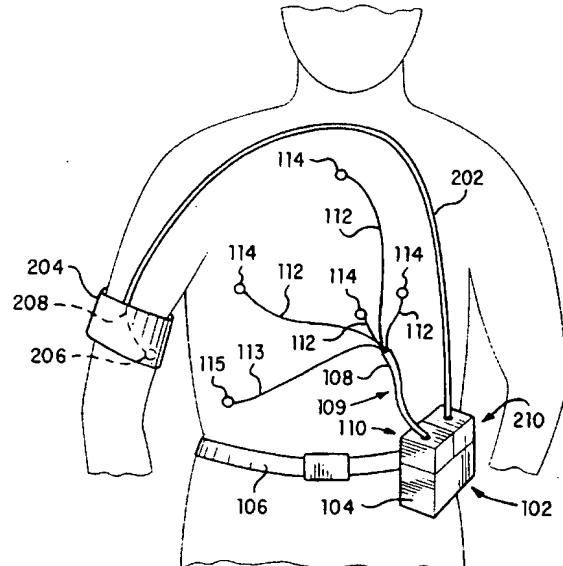


FIG. 1

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This invention relates to monitoring systems for measuring and storing diagnostic parameters of ambulatory patients.

In one combination, this invention relates to patients modular monitoring systems, wherein modular monitoring units can be used either independently of one another, or utilized together with at least one module communicating to one another through an optical interface.

In another combination this invention relates to a system wherein an ambulatory patient's ECG waveform is monitored and analyzed to identify particular abnormalities, both the ECG waveform and analysis data being stored in a nonvolatile memory.

In more detail, in accordance with a first aspect of the present invention, there is provided an ambulatory patient monitoring system, comprising:

- a) a first monitoring means for independently measuring and storing a predetermined first diagnostic parameter of a first patient responsive to a first control algorithm, said first monitoring means including first optical interface means for digital communication, said first monitoring means further including first memory means for storing said first diagnostic parameters;
- b) at least a second monitoring means for measuring a predetermined second diagnostic parameter responsive to a first control signal and storing said second diagnostic parameter responsive to a second control algorithm, said first control signal being generated at a selectively variable repetition rate selectively actuated for predetermined time intervals, said second monitoring means including second optical interface means for digital communication with at least said first monitoring means, said second monitoring means being (1) independently operable for measuring said second diagnostic parameter of a second patient, said second diagnostic parameter being different than said first diagnostic parameter, and (2) positionable in optical alignment with said first monitoring means for measuring said second diagnostic parameter of said first patient responsive to both said first control signal and a second control signal, said second control signal being generated by said first monitoring means and transmitted by said first optical interface means to said second optical interface means, said second monitoring means including second memory means for storing said second diagnostic parameters; and
- c) computing means selectively couplable to both said first and second monitoring means for transferring data therebetween and selectively displaying said first and second diagnostic parameters, said computing means including at least a pair of serial interface ports.

In accordance with a second aspect of the inven-

tion, there is provided an ambulatory patient monitoring system for measuring and storing a plurality of diagnostic parameter values, comprising:

- 5 microprocessor means for determining said diagnostic parameter values;
- 10 nonvolatile memory means coupled to said microprocessor means for storing both said plurality of diagnostic parameter values and a control algorithm, said nonvolatile memory being formed by a plurality of electrically programmable, electrically erasable semiconductor memory devices, said memory devices being all substantially simultaneously electrically erasable;
- 15 random access memory means coupled to said microprocessor means for temporary storage of said control algorithm, said microprocessor means transferring said control algorithm (1) from said nonvolatile memory means to said random access memory means preceding electrical erasure of said nonvolatile memory means, and (2) back to said nonvolatile memory means subsequent to said erasure thereof; and
- 20 sensor means coupled to said microprocessor means for providing measurement data thereto, said microprocessor means calculating said diagnostic parameter values from measurement data.
- 25 In accordance with a third aspect of the invention, there is provided an ambulatory patient monitoring system for measuring and storing a plurality of diagnostic parameter values powered by a portable power source, comprising:
- 30 microprocessor means for determining said diagnostic parameter values;
- 35 memory means coupled to said microprocessor means for storing said plurality of diagnostic parameter values;
- 40 means for stopping and starting operation of said microprocessor means to thereby conserve power from said portable power source; and
- 45 sensor means coupled to said microprocessor means for providing measurement data thereto, said microprocessor means calculating said diagnostic parameter values from said measurement data.
- 50 In accordance with a fourth aspect of the invention, there is provided an ambulatory patient monitoring system for measuring and storing a plurality of electrocardiographic signals powered by a portable power source, comprising:
- 55 microprocessor means for identifying and categorizing abnormalities in said electrocardiographic signals for generating abnormality data;
- 60 memory means coupled to said microprocessor means for storing said electrocardiographic signals and said abnormality data;
- 65 variable clocking means coupled to said microprocessor means for varying an operational speed thereof responsive to a particular function being performed to thereby conserve power from said portable

power source;

signal conditioning means coupled to said microprocessor means for providing said electrocardiographic signals thereto; and

lead means coupled to said signal conditioning means on one end thereof and a patient on an opposing end for coupling said electrocardiographic signals from said patient to said signal conditioning means.

In accordance with a fifth aspect of the invention, there is provided an ambulatory patient monitoring system for measuring and storing a plurality of electrocardiographic signals powered by a portable power source, comprising:

microprocessor means for identifying and categorizing abnormalities in said electrocardiographic signals for generating abnormality;

memory means coupled to said microprocessor means for storing said electrocardiographic signals and said abnormality data;

optical interface means coupled to said microprocessor means for communicating with an external monitoring unit;

signal conditioning means coupled to said microprocessor means for providing said electrocardiographic signals thereto; and

lead means coupled to said signal conditioning means on one end thereof and a patient on an opposing end for coupling said electrocardiographic signals from said patient to said signal conditioning means.

In accordance with a sixth aspect of the invention, there is provided an ambulatory patient monitoring system, comprising at least two substantially independent and separate monitoring units for measuring different diagnostic parameters, each of said monitoring units comprising:

a) microprocessor means for controlling the measurement and storage of predetermined diagnostic parameters;

b) memory means coupled to said microprocessor means for storing said predetermined diagnostic parameters;

c) optical interface means coupled to said microprocessor means for communicating with another of said monitoring unit;

d) signal conditioning means coupled to said microprocessor means for providing said diagnostic parameters thereto; and

e) input means coupled to a patient and having an output coupled to said signal conditioning means.

In accordance with a final aspect of the invention, there is provided an ambulatory patient monitoring system for measuring and storing a plurality of blood pressure values powered by a portable power source and having an inflatable cuff affixable to a patient, comprising:

transducer means coupled to a patient for providing measurement data, said transducer means including (1) an audio transducer for detecting K

sounds, and (2) a pressure transducer fluidly coupled to said inflatable cuff for measuring a plurality of cuff pressure values;

microprocessor means for determining said blood pressure values from said measurement data;

memory means coupled to said microprocessor means for storing said plurality of blood pressure values, said K sounds, and said plurality of cuff pressure values;

means for supplying fluid to a said inflatable cuff, said fluid supply means being actuated responsive to an inflate command control signal from said microprocessor means; and

means for deflating said inflatable cuff responsive to a deflate command signal from said microprocessor means.

Whilst the invention has been described with reference to several different aspects or combination, two or more of these aspects may be combined within and be provided by a single multi-purpose system.

The various aspects and combinations of the invention are described with reference to the accompanying drawings, in which:

Figure 1 is a diagram showing the general construction of an ambulatory monitoring system of the present invention in use;

Figure 2 is a perspective view of part of the ambulatory monitoring system of Figure 1 connected to a control system;

Figure 3 is a perspective view of part of an alternative embodiment of an ambulatory monitoring system according to the present invention;

Figure 4 is a block diagram of an ECG monitoring unit usable in the systems of Figures 1 to 3;

Figure 5 is a block diagram of an ECG analog signal conditioning circuit usable in the systems of Figures 1 to 3;

Figure 6 is a block diagram of the pacemaker packing spike detector usable in the systems of Figures 1 to 3;

Figure 7 is a simplified logic flow diagram usable in the apparatus of this invention for ECG analysis;

Figure 8 is a circuit diagram of an ECG optical interface usable in the apparatus of this invention;

Figure 9 is a block diagram of a blood pressure monitoring unit suitable for use in the apparatus of this invention;

Figure 10 is a block diagram of a K sound signal conditioning circuit suitable for use in the apparatus of this invention;

Figure 11 is a simplified logic flow diagram for the blood pressure monitoring unit of Figure 9; and

Figure 12 is a simplified logic flow diagram for use in the rapid blood pressure measurement method hereinafter described.

Referring to the Figures, monitoring system 100 is modular in construction to provide at least three

monitoring systems in one, and having the capacity to greatly exceed that number. In the configuration shown in FIG. 1, the portable portion 102 of system 100 provides for the simultaneous and coordinated measurement of both ECG and blood pressure parameters, functioning as a single instrument.

The ECG monitoring unit 110 functions as the master unit, with the blood pressure unit 210 defining a slave unit. As a slave unit, and in addition to making measurements in accordance with a programmed protocol, the blood pressure unit is responsive to predetermined events identified by the master ECG monitoring unit 110 for initiating a blood pressure measurement. Modules may be utilized independently, or placed in various combinations to form a monitoring instrument tailored to suit the diagnostic requirements for a particular patient.

Referring now to FIG. 1, there is shown the portable portion 102 of ambulatory monitoring system 100 as might be worn by a patient. The ECG monitoring unit 110 and the blood pressure monitoring unit 210 are disposed in side-by-side relationship within a carrying pouch 104, and releasably secured to the patient by means of a belt or strap 106. A plurality of ECG electrodes 114, each having a respective lead 112 of a multiple lead cable 108 defining ECG lead pairs, are part of an ECG electrode assembly 109, coupled to the ECG monitoring unit 110. Electrode assembly 109 further includes a reference electrode 115 coupled to a lead 113.

The blood pressure monitoring unit 210 includes an inflatable cuff 204 which carries an audio transducer 206, positioned adjacent the patient's arm, for converting the K sounds to electrical signals transmitted to monitoring unit 210 through an electrical cable 208. The cuff 204 is inflated and deflated through a hose 202 coupled to a fluid pump or compressed fluid supply and a bleed valve. The transducer cable 208 may be integrated into the hose 202, wherein cable 208 is coupled to an exterior surface of hose 202, extends through the fluid carrying lumen, or through a separate lumen formed therein.

Referring now to FIG. 2, there is shown ambulatory patient monitoring system 100 wherein a personal-type computer 120 is coupled to respective diagnostic parameter measuring units 110, 210, by means of optically isolated serial data links 124, 224. Bidirectional communication between the monitoring units 110, 210 and the personal-type computer 120 is provided through respective serial interfaces 48, 252 (shown in FIGS. 4 and 9) which are coupled to respective serial ports of computer 120 through respective connectors 118, 218 and serial data cables 124, 224. The physician utilizes the personal-type computer 120 to enter particular patient information, which is relevant to identifying that patient and the data collected therefrom, as well as enter particular measurement protocols, operating parameters, and event trig-

gering data, or retrieve data from the monitoring units 110, 210.

Subsequent to stored data being downloaded from measuring units 110 and 210, the physician can display for any time period, the ECG waveform, the heart rate, as well as display the number and time of day of the occurrence of abnormal conditions. Such abnormal conditions as arrhythmias, absence of particular ECG waveform components, and pacemaker malfunctions are separately identified and classified.

Referring now to FIG. 3, there is shown an advantage of the optical interface 50, 254 for units 110, 210, respectively, in combination with the real time mode of the units. The patient may be provided with a modem 130 and an optical interface unit 122, coupled to modem 130 by means of a serial data cable 128 for communicating with the ECG monitoring unit 110.

Optical interface unit 122 includes an optically transmissive window 126, which complements the window 116 of the monitoring unit 110, and is provided with circuitry to permit optically isolated communication through the telephone line 132, to the physician's personal-type computer 120, or some other computing system or digital equipment.

Turning now to FIG. 4, there is shown a block diagram for the ECG monitoring unit 110. The ECG electrode cable 108 carries signals from two pairs of electrodes 114, defining two ECG channels. The leads representing these two ECG channels are carried by the cable 108 and are coupled to an impedance switching network 10. Impedance switching network 10 defines a digitally controlled switch capable of injecting a small test current back through the leads to the patient. This test current establishes a voltage across a respective pair of leads which is used to measure the impedance across the electrodes. Either the substantially constant voltage of the impedance measurement or the ECG waveform signals, are coupled to respective signal conditioning circuits 12, 18 by means of respective coupling lines 7, 9.

As shown in FIG. 5, the signal conditioning circuit 12 comprises a fixed gain amplifier 300 having an input coupled to the coupling line 7, and an output coupled to a high pass filter circuit 302. High pass filter circuit 302 has a lower cut-off frequency approximating .05 hertz. Variable gain amplifier stage 304 is digitally programmable, having a gain control digital link 13 coupled to microprocessor 30. The variable gain of amplifier 304 stage may be adjustable within a range of .5 - 21, and preferably within a range of 3 to 12.5. The output of variable gain amplifying stage 304 is coupled to a low pass filter 306, having a frequency cut-off of approximately 40 hertz.

The gain of variable gain amplifier stage 304 is adjusted by microprocessor 30 by sampling the ECG signals with the gain set at a minimum value. If the peak amplitude of the detected R-wave is less than

a predetermined value, the gain is increased by an incremental value. If at this increased gain step the R-wave amplitude is less than a second predetermined value, the gain is advanced another step, otherwise it will remain.

Since the second ECG channel signal conditioning circuit 18 is identical to that of circuit 12, such has not been shown. The variable gain portion of the signal conditioning circuit 18 is controlled through a digital link 15 coupled to microprocessor 30, as shown in FIG. 1, to provide independent and variable gain for that respective channel. The output 14, 20 of each of the signal conditioning circuits 12 and 18 are respectively coupled to an analog-to-digital multiplexing converter 16 by means of the respective coupling lines 14 and 20. In addition to the respective output lines 14, 20 of the signal conditioning circuits 12, 18, the output of a battery monitoring circuit 17 is coupled to one input of the multiplexing A-to-D converter 16 for providing battery condition data to microprocessor 30. When microprocessor 30 detects the low battery signal, it stores the alarm condition and the time of day that it occurred, which is recovered when the physician down loads the memory. Multiplexing A-to-D converter 16 sequentially converts the analog signals on each of the input lines to a multi-bit digital representation thereof, for communication to microprocessor 30 through the coupling line 26.

The ECG monitoring unit 110 includes a pacemaker spike detector circuit 24 having an input coupled to the output line 20 of the channel 2 signal conditioning circuit 18. As shown in FIG. 6, the pacemaker spike detector circuit 24 includes a high pass filter circuit 308 having an input coupled to line 22. High pass filter 308 is provided with a frequency cutoff at 20 Hertz to remove the ECG signal and any muscle artifacts which might be present in the signal. The output of high pass filter 308 is coupled to an absolute value amplifier 310. Absolute amplifier 310 has a gain value approximating 500 for amplifying the pacemaker spike signal to a magnitude within the range of 10 through 500 millivolts. The output of absolute value amplifier 310 is coupled to the input of a peak detector 312. Peak detector 312 establishes a threshold value which must be exceeded for a digital logic level signal to be output on line 25 for coupling with microprocessor 30. The pulse provided to microprocessor 30 through coupling line 25 is subsequently analyzed to determine if the signal provided on line 25 is in fact a signal representing the pacemaker spike. A pacer signal from a pacemaker has a fixed pulse width, typically in a range between 0.5 and 2.0 milliseconds, the microprocessor 30 therefore disregards any signal supplied by pacemaker spike detector circuit 24 which is outside that range.

ECG data supplied through line 26 from the analog-to-digital converter 16 is monitored to determine whether the gain is properly set in the respective sig-

nal conditioning circuits 12 and 18, the microprocessor outputting control signals on respective control lines 13, 15 for selecting the appropriate gain values for input to the signal conditioning circuits 12, 18. Data storage memory 46 provides 4 megabytes of non-volatile memory for storage of the ECG and analysis data within monitoring unit 110.

Referring now to FIG. 7, there is shown, a simplified flow diagram of the ECG data processing steps carried out by microprocessor 30. The digitized data representing the ECG signal from either one of the two input channels (each of the channels being processed alternately) is provided from the input block 150 to the smoothing filter block 152 for enhancing the signal to noise ratio. The smoothed data is supplied to the data compression block 166, wherein a data bit reduction procedure is carried out. The compressed data from block 166 is provided to the storage output block 168, providing the data for storage within the data storage memory 46, followed by the step of reducing the frequency of clock circuit 32, in block 167.

The filtered data from block 152 is also supplied to the beat detection decision block 154. When a beat is detected, the data is transmitted from decision block 154 to the beat classification block 156, the heart rate computation block 164 and block 170 where the clock frequency is increased. The heart rate computed in block 164 is transmitted to data compression block 166 for subsequent storage in the data storage memory 46. Classification block 156 identifies arrhythmias from the beat timing supplied from the beat detection block 154, classifying the beat into predetermined categories. The arrhythmia type identified by the beat classification block 156 is transmitted to the data compression block 166 for storage in the data storage memory 46. Additionally, the arrhythmia type is transmitted to the rhythm classification block 162. The output of rhythm classification block 162 is similarly transmitted to the data compression block 166 for storage in data storage memory 46. The output of the beat classification block 162 is also supplied to the blood pressure trigger detection decision block 158, and if the type of arrhythmia or rhythm identified by block 162 matches that which has been predetermined to require a simultaneous blood pressure measurement, previously entered by the physician, then the signal transmission output block 160 is enabled, for sending a trigger control signal to the blood pressure unit.

Referring additionally to FIG. 4, microprocessor 30 is coupled to a clock circuit 32, which may be provided internal to microprocessor 30 or as an ancillary device. The clock signals output from clock circuit 32 are supplied to microprocessor 30 through coupling line 34. Microprocessor 30 includes an output line 32 coupled to clock circuit 32 for controlling the clock frequency supplied therefrom.

As is well known in the art, complementary metal oxide microprocessor devices consume power in direct relation to their operating speed, thus it is possible to reduce the power consumption of microprocessor 30 by maintaining a low clock frequency. This however, would have a detrimental effect on performing data compression and arrhythmia analysis in real time. To achieve the advantages of a reduced clock frequency, while obviating the disadvantage such would have on processing intensive functions, the clock speed control output 32 is utilized to adapt the clock circuit frequency to the function being performed by the microprocessor. Thus, responsive to detection of heart beats in decision block 154, the frequency of clock 32 is increased to support the real time processing of the ECG data. It should be understood that the frequency reduction step of block 169 is not reached until all of the data, raw and analysis, has been stored.

Thus, for high powered processing (significant computation), the clock circuit is operated at its highest frequency, 8 megahertz for example, and during periods, between heartbeat signals, the clock frequency may be reduced down to its lowest operating frequency, such as 32 kilohertz.

Microprocessor 30 provides output data which is stored in the programmable read-only memory 46, through the data bus 38 with appropriate addressing supplied through the address bus 37. Microprocessor 30 is further supported by 128-kilobytes of random access memory 42 as temporary storage for use in the data compression and arrhythmia analysis processing. The operations of microprocessor 30 are controlled by a program stored in read-only program memory 44, coupled to the data bus 38 and address bus 37. Each of the memory subsystems 42, 44 and 46 are each coupled to data bus 38 and address bus 37. Also coupled to data bus 38 is a general I/O interface 36 which is selected by means of the I/O port selection control line 39, coupled to microprocessor 30. The input to general interface 36 is coupled to a momentary push-button switch 35 for coupling a reference potential thereto. Switch 35 functions as an event switch, which functions as an event marker for the ECG signal.

ECG monitoring unit 110 includes a serial interface connector 118 for coupling with an external computing device. Connector 118 is coupled to serial interface 48 by means of a respective serial input and output line, the serial interface being coupled in turn with microprocessor 30 by means of respective input and output lines 43 and 45. Optical interface 50 is coupled to microprocessor 30 by means of respective input and output lines 40 and 41. The optical interface 50 converts electrical signals transmitted from microprocessor 30 into optical signals which are transmitted through the transmissive window 116 to a slave module, such as the blood pressure measuring unit

210. Optical signals from the slave module pass through transmissive window 116 and are received by an optical detector, such as a phototransistor, for conversion to electrical signals which are transmitted to microprocessor 30 by line 40.

5 Referring now to FIG. 8, there is shown the optical communications interface 50 coupled to microprocessor 30. Optical interface 50 includes three light emitting diodes 70, 72 and 74, each coupled in series with a respective current-limiting resistor 76, 78 and 80. Each of resistors 76, 78 and 80 being coupled to a common power supply terminal 82 for receiving the positive power supply voltage thereon. The opposing end of light emitting diodes 70, 72 and 74 being coupled to the output of a respective tri-state buffer amplifier 84, 86 and 88.

10 The light emitting diodes are turned off when the interface is disabled, by means of the interface enable control line 92 coupling microprocessor 30 to each of the tri-state control inputs 83, 85 and 87 of the respective tri-state amplifiers 84, 86 and 88 coupled to light emitting diodes 70, 72 and 74.

15 When microprocessor 30 outputs a logic low level signal on line 92, each of the drivers 84, 86 and 88 is enabled, turning light emitting diode 70 on, allowing transmission of serial data from line 96 through the light emitting diode 72, and transmission of the serial clock from line 98 through light emitting diode 74. Serial data is received from the slave module, such as the blood pressure monitoring unit 210, through the phototransistor 73. Phototransistor 73 is coupled in series with a load resistor 75, which is in turn coupled to the positive power supply input terminal 82. The emitter of the phototransistor 73 is coupled to the ground reference potential for the system. The output of phototransistor 73, taken from the collector thereof, is coupled directly to microprocessor 30 on interrupt line 95.

20 The presence of a signal on interrupt line 95 alerts the microprocessor to the transmission of data from the slave module. Additionally, the output of phototransistor 73 is coupled to the input of the tri-state buffer amplifier 90 for transmission through the serial input line 94 to microprocessor 30. As with the other tri-state buffer amplifiers, amplifier 90 includes a tri-state control input 91 which is coupled to the interface enable control line 92. When the slave module initiates an optical transmission to ECG unit 110, the received signal changes the logic state of interrupt line 95 from a high to a low level, generating the interrupt signal internal the microprocessor 30. Microprocessor 30 responds by changing the logic level of the interface enable line 92 from a high to a low, illuminating light emitting diode 70 to indicate to the slave module that microprocessor 30 is ready to receive data, the data being synchronized with the serial clock signal of microprocessor 30, transmitted by light emitting diode 74. With respect to the block dia-

gram of FIG. 4, output lines 92, 96 and 98 are represented by coupling line 41, and input lines 94 and 95 are represented by coupling line 40.

Each of units 110 and 210 are capable of using their respective optical interface to automatically detect the presence of the other respective unit. When unit 110, for instance, is turned on and completes initial self test and calibration functions, a signal is transmitted by the optical interface 50. If after a predetermined delay no response is received, ECG unit 110 operates as an independent unit, unless an interrupt signal is received on line 95 at some later time.

Referring now to FIG. 9, there is shown a block diagram of the blood pressure monitoring unit 210. A transducer assembly 214 includes an audio transducer 206, which may be a microphone, for converting the K sounds into electrical signals transmitted by electrical cable 208 to signal conditioning circuit 270, which performs amplification and filtering functions. The output of signal conditioning circuit 270 is coupled to analog-to-digital multiplexing converter 266 through coupling line 268. Coupling line 268 represents the output of several signals from signal conditioning circuit 270. The digitized output of the analog-to-digital multiplexing converter 266 is supplied to microprocessor 262 through coupling line 264. Microprocessor 262 provides a control signal to signal conditioning circuit 270 by means of coupling line 271 for controlling the amplification gain thereof.

The transducer or sensor assembly 214 further includes a pressure transducer 212 for measuring the inflation pressure of cuff 204 through hose 202. The electrical output of pressure transducer 212 is coupled to amplifier 274 through coupling line 232. The output of amplifier 274 is coupled to analog-to-digital multiplexing converter 266 through coupling line 272. As in the ECG monitoring unit 110, blood pressure monitoring unit 210 includes a battery monitoring circuit 248 having an output coupled to an analog-to-digital multiplexing converter 266 through coupling line 249. Microprocessor 262 stores the alarm condition and time of day it occurred with the blood pressure data.

Microprocessor 262 may be an 8-bit microprocessor having internal serial interface circuitry. Microprocessor 262 outputs a pump control signal on line 240 which is coupled to a driver amplifier 242. The output of the driver amplifier 242 is coupled to the pump 244 by means of the coupling line 243. Pump 244 pumps fluid through an output conduit 245 through bleed valve 246 and conduit 236 to pressure transducer 212, for coupling with cuff 204 through hose 202.

When an occlusion pressure is reached, pump 244 is shut down, by the change in state of the control signal output on line 240. Subsequently, a control signal is output on line 261 which is supplied to driver amplifier 260. Driver amplifier 260 provides an output on line 247 for controlling the bleed valve 246, which

controls the release of fluid from cuff 204 through hose 202 on conduit 236.

The rate at which fluid pressure is bled from the cuff 204 is controlled by the outlet orifice of bleed valve 246, with the increments of pressure at which the microprocessor checks for the presence of K sounds being controlled by the length of time that the bleed valve is opened, that length of time being the time between beats. When the pressure is dropped, the microprocessor checks for detection of a K sound, and then proceed to open the bleed valve for the next interval between beats. Each incremental pressure value is stored in memory during the measurement procedure.

Referring now to FIG. 10, there is shown, a block diagram of the signal conditioning circuit 270. The electrical signals from audio transducer 206 are supplied by line 208 to a variable gain amplifier stage 320. The gain of amplifier 320 is controlled by a signal from microprocessor 262 through the coupling line 271. The output of variable gain amplifier 320 is coupled to a band pass filter 324 by means of line 322. The output of band pass filter 324 is coupled to one channel of analog-to-digital multiplexing converter 266 through coupling line 328, providing the K sound audio signals to microprocessor 262 for storage and subsequent analysis.

The provision for storing actual K sounds is an important new feature for ambulatory blood pressure monitoring units. In conventional systems the physician manually takes a patient's blood pressure while the patient is at rest, comparing the manual measurement with the ambulatory unit's measurement, but now can compare measurements on an active patient. The output of band pass filter 324 is supplied to absolute value amplifier 330 through coupling line 326. Absolute value amplifier 330 converts the bipolar audio signal output from filter 324 into a unipolar signal and outputs a signal representing the envelope thereof. The K sound envelope is coupled to a respective channel of analog-to-digital multiplexing converter 266 through coupling line 334. The output of absolute value amplifier 330 is also coupled to peak detector 336 by means of coupling line 332. Peak detector 336 provides a pulse output responsive to the K sound envelope signal exceeding a predetermined threshold. The output of peak detector 336 is coupled to yet another channel of analog-to-digital multiplexing converter 266 by means of coupling line 338. Each of the signal lines 328, 334 and 338 are represented by the signal line 268 in the block diagram of FIG. 9.

Referring back to FIG. 9, there is shown, a real time interrupt generator 276 coupled to microprocessor 262 by means of the coupling line 277. Real time interrupt generator 276 forms part of a power saving subsystem of blood pressure monitoring unit 210. Blood pressure monitoring unit 210 is periodically put

in a "sleep" mode wherein the microprocessor operation is stopped and the current draw is dropped to the microamp level, providing a substantial power savings. Subsequently, responsive to an output from real time interrupt generator 276 the microprocessor is "awakened" to perform housekeeping chores, such as incrementing counters and checking status of communication ports, and taking blood pressure measurements, as required.

Referring now to FIG. 11, there is shown, a simplified flow diagram representing the cyclic operation of microprocessor 262. Responsive to an output from real time interrupt generator 278 a reset of microprocessor 262 is initiated at block 172. The signal from real time interrupt generator 276 is a repetitive clock signal defining a predetermined increment of time, for example, 0.5 seconds. Thus, subsequent to initiation of the reset defined by block 172, the time of day counter is incremented in block 174. The incremented counter of block 174 provides a time of day which is compared in block 176 with a selected measurement protocol to determine if it is time for a blood pressure measurement to be taken. If a True condition results, then the microprocessor's activity is controlled by the blood pressure measurement routine indicated by block 178.

Subsequent to block 178 being completed, or subsequent to a Not True result in block 176, the microprocessor then tests, in block 180, whether the event switch has been operated. If the event switch has been operated then the microprocessor proceeds to perform a blood pressure measurement as indicated in block 182. From block 182, or if the event switch has not been operated, the microprocessor checks the optical interface to determine if the ECG unit 110 is signalling that a blood pressure measurement should be taken. If such a predetermined abnormality has occurred, then, as indicated in block 186, the microprocessor performs a rapid blood pressure measurement, described with reference to FIG. 12. Subsequently, the microprocessor then looks to the serial interface 252 to determine if it is active, as indicated in block 188. If the result of this test is True, then the microprocessor performs the necessary communications operations, as indicated in block 190. If the test of block 188 is Not True, or such communications is completed, the microprocessor is then put in a stop mode, as indicated by block 192, wherein its functions cease and power consumption is substantially reduced.

The event switch 235, shown in FIG. 9, is a momentary push-button switch coupled in series with a load resistor 231 between the positive power supply voltage, on one end of resistor 231, and the power supply reference coupled to the opposing terminal of switch 235. Coupled to the node between switch 235 and load resistor 231 there is provided an input line 233 coupled to an input terminal of microprocessor

262. By this arrangement, line 233 is held at a high logic level when switch 235 is open, and brought to a low logic level when the contacts of switch 235 are closed.

5 Optical interface 254, coupled to microprocessor 262, is constructed to complement that of optical interface 50 of the ECG monitoring unit 110. An optical signal transmitted from light emitting diode 74 of optical interface 50, through light transmissive window 216 of blood pressure monitoring unit 210 is received by a respective phototransistor for transmission of the clock signal to microprocessor 262 through line 259. The received clock signal being utilized for synchronization of the serial transmission sent to ECG monitoring unit 110 and the transmission received therefrom. The serial data transmitted from microprocessor 262 is transmitted to optical interface 254 by line 255, wherein a light emitting diode is driven to provide an optical output transmitted through transmissive window 216 to ECG monitoring unit 110 for receipt by phototransistor 73.

10 25 A serial interface 252 is provided for communication with such devices as the personal type computer 120 shown in FIG. 1. The serial interface connector 218 provides the means for coupling serial input and output lines, through serial interface 252, to respective serial input and output ports of microprocessor 262. Serial data from microprocessor 262 is carried by line 253 to serial interface 252, and serial data therefrom is transmitted to microprocessor 262 by line 241.

15 30 35 Blood pressure measurement data, the raw audio signals, and the K sound envelope, are all stored in programmable read-only memory 256. Programmable read-only memory 256 is an electrically erasable programmable read-only memory for providing non-volatile storage of the blood pressure measurement data. Additionally, the software required to operate microprocessor 262 is stored within programmable read-only memory 256, along with the selected measurement protocol entered by the physician through the personal type computer 120. Subsequently, the data is read from memory 256 and transmitted through serial interface 252 for display, and possible subsequent processing by personal computer 120. Programmable ROM memory 256 is coupled to microprocessor 262 through the bi-directional data bus 250 and address bus 251. Further, microprocessor 262 is coupled to 128 kilobit random access memory 258 by means of bi-directional address bus 250 and address bus 251.

40 45 50 55 Prior to erasure of programmable read-only memory 256, the operating program for microprocessor 262 is transferred from read-only memory 256 to random access memory 258. Subsequent to the transfer of the operating program, programmable read-only memory 256 is erased, to permit use on a new patient, or to gather another 24-hour accumulation of

data on the same patient. While the operating program is stored in random access memory 258 such can be modified with new measurement protocols entered by the physician through serial interface 252. Additionally, if the operating program is to be replaced, such replacement may be entered through interface 252 for storage in programmable read-only memory 256, subsequent to erasure thereof.

Referring now to FIG. 12, there is shown a flow diagram for the rapid blood pressure measurement selected to be utilized by the physician, responsive to particular transient abnormal conditions identified by the ECG monitoring system 110. Responsive to the ECG monitoring unit triggering a blood pressure measurement at entry block 340, the pump 244 is turned on, as indicated in block 342. Subsequent to the pump turn on, and after a predetermined delay to inflate the cuff to a predetermined pressure, microprocessor 262 tests to see if K sounds are present, as indicated in block 344. If K sounds are present, the inflation provided by the energization of pump 244 continues until K sounds are no longer detected. When K sounds are no longer detected, pump 244 is turned off, as indicated in block 346. Immediately thereafter, the cuff is deflated through bleed valve 246 in predetermined, relatively large steps, in the approximating range of 5.0 - 10.0 millimeters of Hg, indicated in block 348. At each incremental drop in cuff pressure, microprocessor 262 tests to determine if any K sounds are present, as indicated in block 350, until K sounds are detected. When K sounds are detected the pressure reading, as indicated by an output from the pressure transducer 212, is stored in memory, as indicated in block 352. By utilizing this rapid deflation of cuff 204 in order to establish a coarse approximation of the systolic blood pressure, a clinically significant measurement is provided for determining whether a hypotensive condition has coincided with a transient condition of electrocardioactivity.

Claims

1. An ambulatory patient monitoring system, comprising:
 - a. first monitoring means for independently measuring and storing a predetermined first diagnostic parameter of a first patient responsive to a first control algorithm, said first monitoring means including first optical interface means for digital communication, said first monitoring means further including first memory means for storing said first diagnostic parameters;
 - b. at least a second monitoring means for measuring a predetermined second diagnostic parameter responsive to a first control signal and storing said second diagnostic para-

meter responsive to a second control algorithm, said first control signal being generated at a selectively variable repetition rate selectively actuated for predetermined time intervals, said second monitoring means including second optical interface means for digital communication with at least said first monitoring means, said second monitoring means being (1) independently operable for measuring said second diagnostic parameter of a second patient, said second diagnostic parameter being different than said first diagnostic parameter, and (2) positionable in optical alignment with said first monitoring means for measuring said second diagnostic parameter of said first patient responsive to both said first control signal and a second control signal, said second control signal being generated by said first monitoring means and transmitted by said first optical interface means to said second optical interface means, said second monitoring means including second memory means for storing said second diagnostic parameters; and

c. computing means selectively couplable to both said first and second monitoring means for transferring data there between and selectively displaying said first and second diagnostic parameters, said computing means including at least a pair of serial interface ports.

2. The ambulatory patient monitoring system as recited in Claim 1 where said computing means includes third optical interface means for selectable coupling with either said first or second monitoring means for transmitting data therebetween.
3. The ambulatory patient monitoring system as recited in Claim 1 where said first monitoring means includes:
 - a. first serial interface means for said selected coupling with one of said pair of serial interface ports of said computing means;
 - b. first microprocessor means coupled to (1) said first serial interface means, (2) said first optical interface means, and (3) said first memory means for transmission of digital data therebetween;
 - c. signal conditioning means coupled to said microprocessor means for amplifying, filtering and converting analog input signals to digital signals, said microprocessor means analyzing said digital signals to identify and categorize any of said digital signals representing any of a plurality of abnormal conditions; and,
 - d. a plurality of electrodes coupled to said signal conditioning means and being affixable to said first patient for conducting electrocardio-

graphic signals therefrom.

4. The ambulatory patient monitoring system as recited in Claim 1 where said second monitoring means includes second serial interface means for selective coupling with one of said pair of serial interface ports of said computing means for (1) reading data stored in said second memory means, (2) erasing said second memory means, (3) transmitting a replacement for said second control algorithm to said second monitoring means, (4) entering patient identification data, and (5) entering measurement protocols.

5. An ambulatory patient monitoring system for measuring and storing a plurality of diagnostic parameter values, comprising:

- microprocessor means for determining said diagnostic parameter values;
- nonvolatile memory means coupled to said microprocessor means for storing both said plurality of diagnostic parameter values and a control algorithm, said nonvolatile memory being formed by a plurality of electrically programmable, electrically erasable semiconductor memory devices, said memory devices being all substantially simultaneously electrically erasable;
- random access memory means coupled to said microprocessor means for temporary storage of said control algorithm, said microprocessor means transferring said control algorithm (1) from said nonvolatile memory means to said random access memory means preceding electrical erasure of said nonvolatile memory means, and (2) back to said nonvolatile memory means subsequent to said erasure thereof; and,
- sensor means coupled to said microprocessor means for providing measurement data thereto, said microprocessor means calculating said diagnostic parameter values from said measurement data.

6. An ambulatory patient monitoring system for measuring and storing a plurality of diagnostic parameter values powered by a portable power source, comprising:

- microprocessor means for determining said diagnostic parameter values;
- memory means coupled to said microprocessor means for storing said plurality of diagnostic parameter values;
- means for stopping and starting operation of said microprocessor means to thereby conserve power from said portable power source; and,
- sensor means coupled to said microprocessor means for providing measurement data thereto, said microprocessor means calculating

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said diagnostic parameter values from said measurement data.

7. An ambulatory patient monitoring system for measuring and storing a plurality of electrocardiographic signals powered by a portable power source, comprising:

- microprocessor means for identifying and categorizing abnormalities in said electrocardiographic signals for generating abnormality data;
- memory means coupled to said microprocessor means for storing said electrocardiographic signals and said abnormality data;
- variable clocking means coupled to said microprocessor means for varying an operational speed thereof responsive to a particular function being performed to thereby conserve power from said portable power source;
- signal conditioning means coupled to said microprocessor means for providing said electrocardiographic signals thereto; and,
- lead means coupled to said signal conditioning means on one end thereof and a patient on an opposing end for coupling said electrocardiographic signals from said patient to said signal conditioning means.

8. An ambulatory patient monitoring system for measuring and storing a plurality of electrocardiographic signals powered by a portable power source, comprising:

- microprocessor means for identifying and categorizing abnormalities in said electrocardiographic signals for generating abnormality data;
- memory means coupled to said microprocessor means for storing said electrocardiographic signals and said abnormality data;
- optical interface means coupled to said microprocessor means for communicating with an external monitoring unit;
- signal conditioning means coupled to said microprocessor means for providing said electrocardiographic signals thereto; and,
- lead means coupled to said signal conditioning means on one end thereof and a patient on an opposing end for coupling said electrocardiographic signals from said patient to said signal conditioning means.

9. An ambulatory patient monitoring system, comprising:

- at least two substantially independent and separate monitoring units for measuring different diagnostic parameters, each of said monitoring units comprising:
 - a. microprocessor means for controlling the measurement and storage of predetermined diagnostic parameters;

b. memory means coupled to said microprocessor means for storing said predetermined diagnostic parameters;
c. optical interface means coupled to said microprocessor means for communicating with another of said monitoring unit;
d. signal conditioning means coupled to said microprocessor means for providing said diagnostic parameters thereto; and,
e. input means coupled to a patient and having an output coupled to said signal conditioning means.

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10. An ambulatory patient monitoring system for measuring and storing a plurality of blood pressure values powered by a portable power source and having an inflatable cuff affixable to a patient, comprising:

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transducer means coupled to a patient for providing measurement data, said transducer means including (1) an audio transducer for detecting K sounds, and (2) a pressure transducer fluidly coupled to said inflatable cuff for measuring a plurality of cuff pressure values;

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microprocessor means for determining said blood pressure values from said measurement data;

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memory means coupled to said microprocessor means for storing said plurality of blood pressure values, said K sounds, and said plurality of cuff pressure values;

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means for supplying fluid to a said inflatable cuff, said fluid supply means being actuated responsive to an inflate command control signal from said microprocessor means; and,

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means for deflating said inflatable cuff responsive to a deflate command signal from said microprocessor means.

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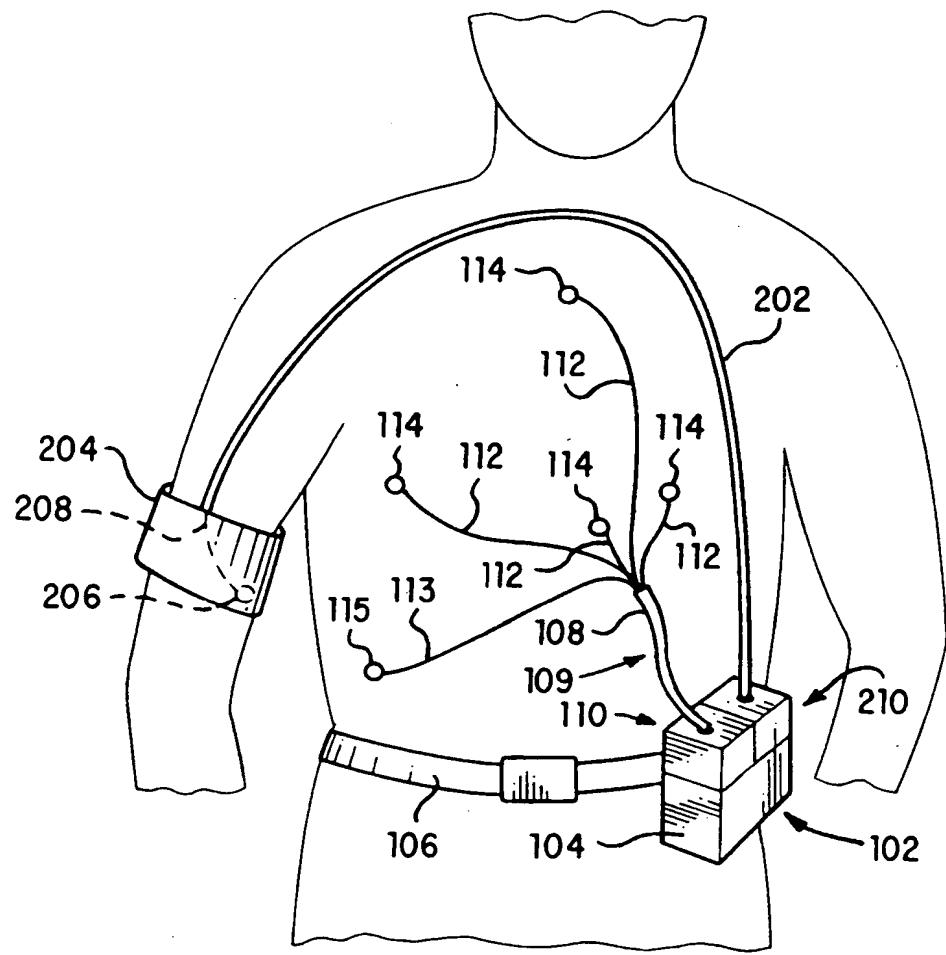


FIG. 1

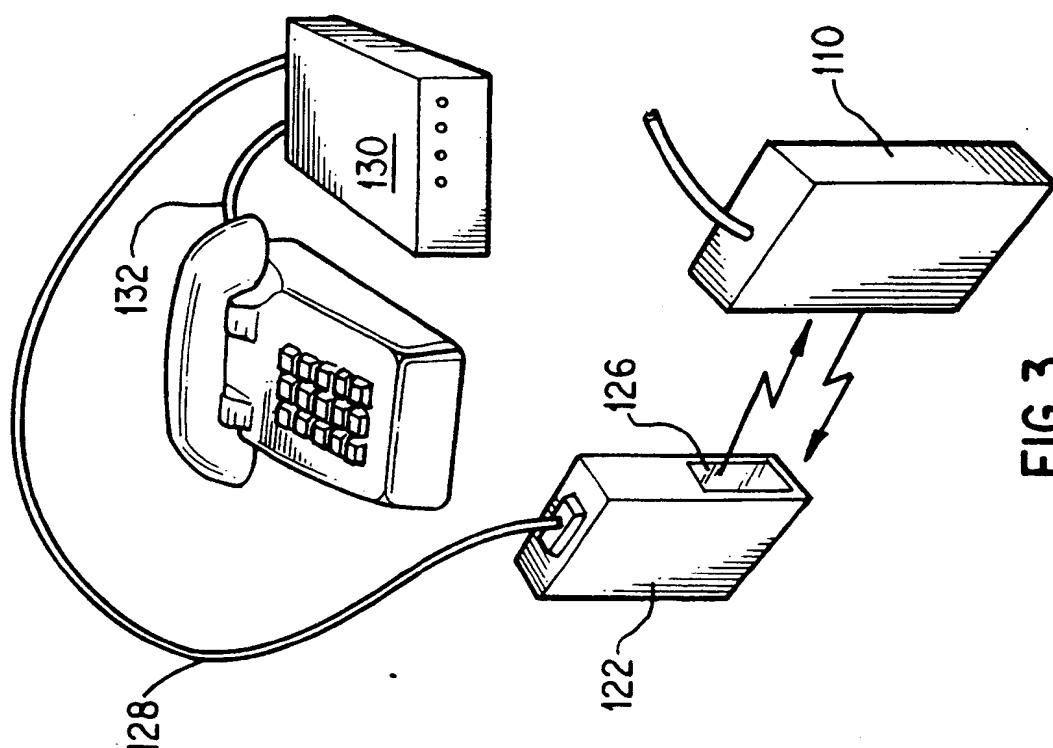


FIG. 3

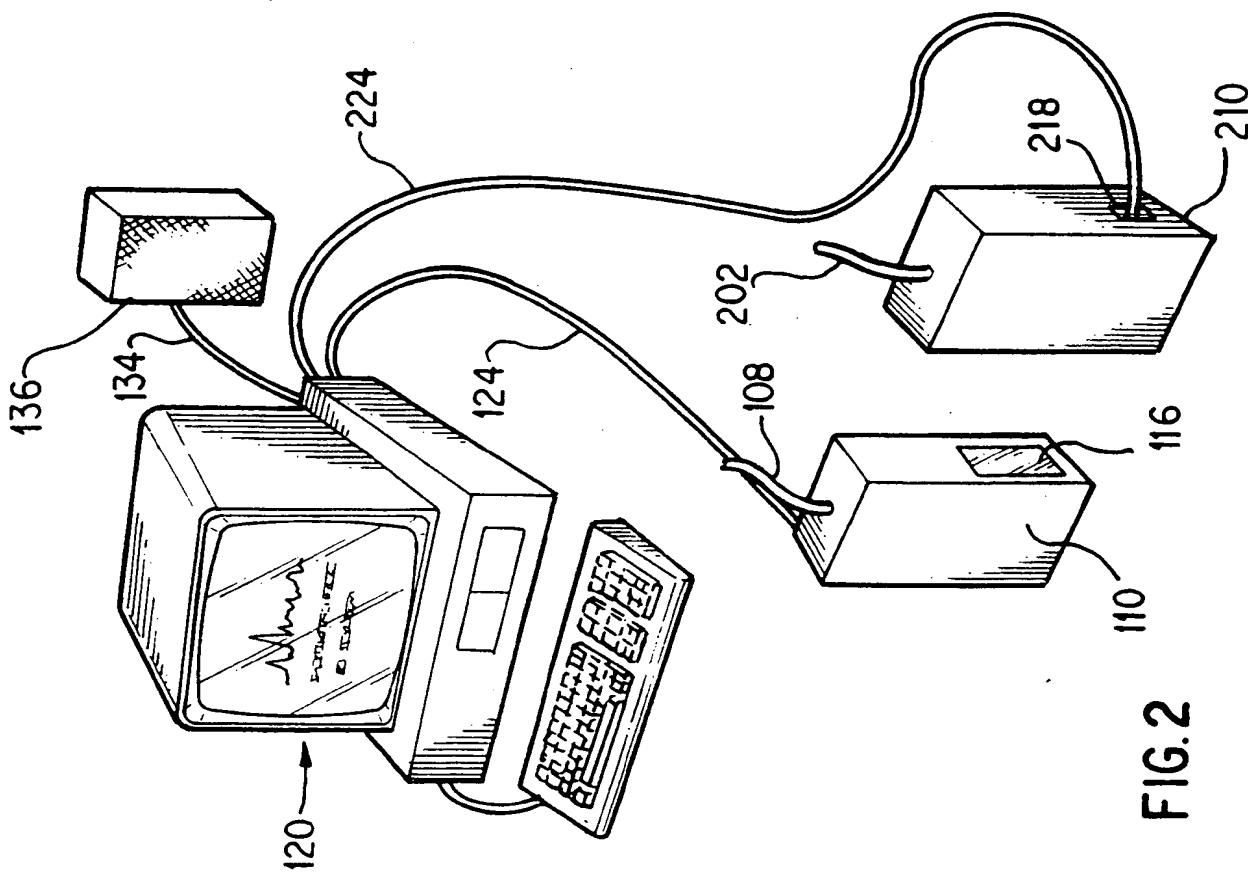


FIG. 2

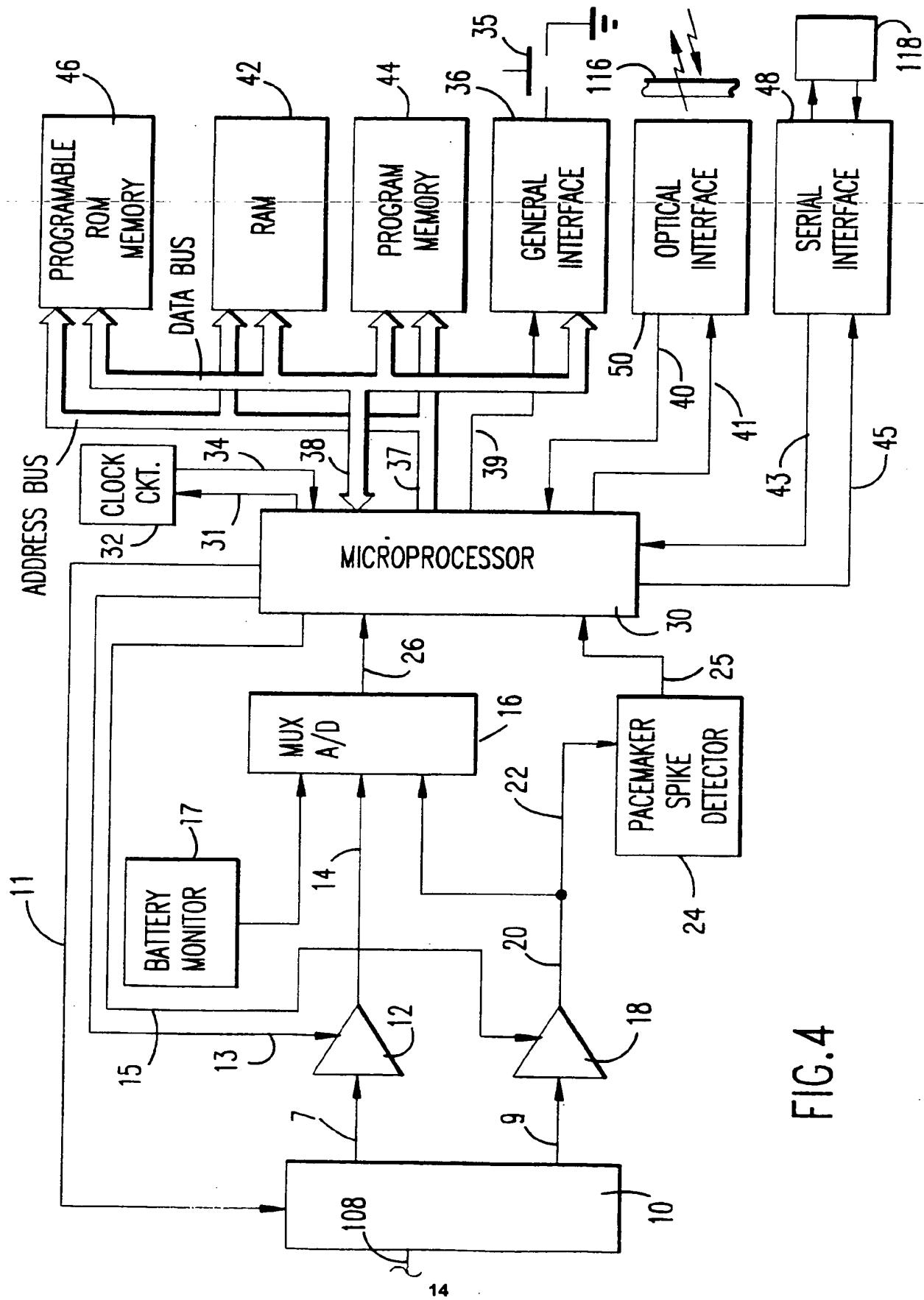


FIG. 4

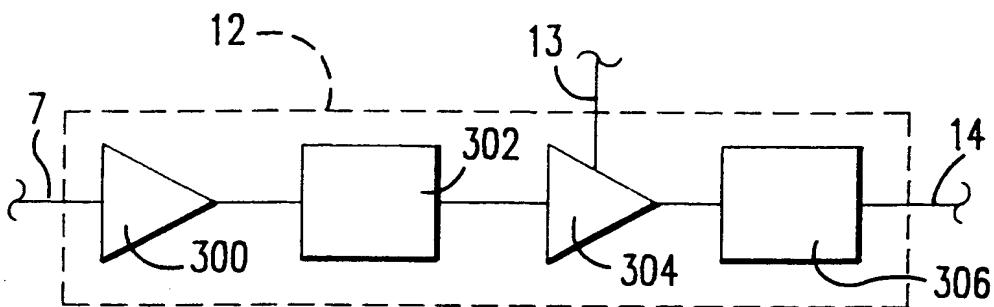


FIG.5

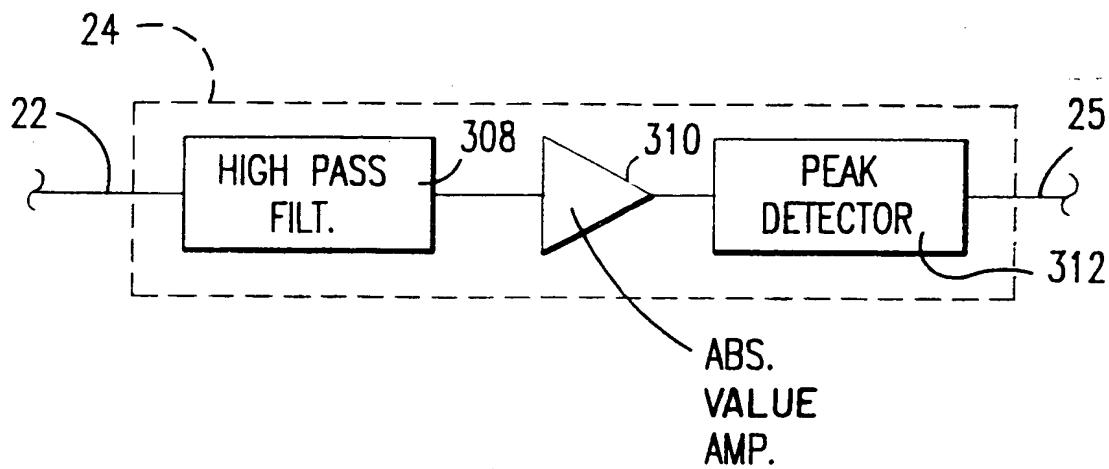


FIG.6

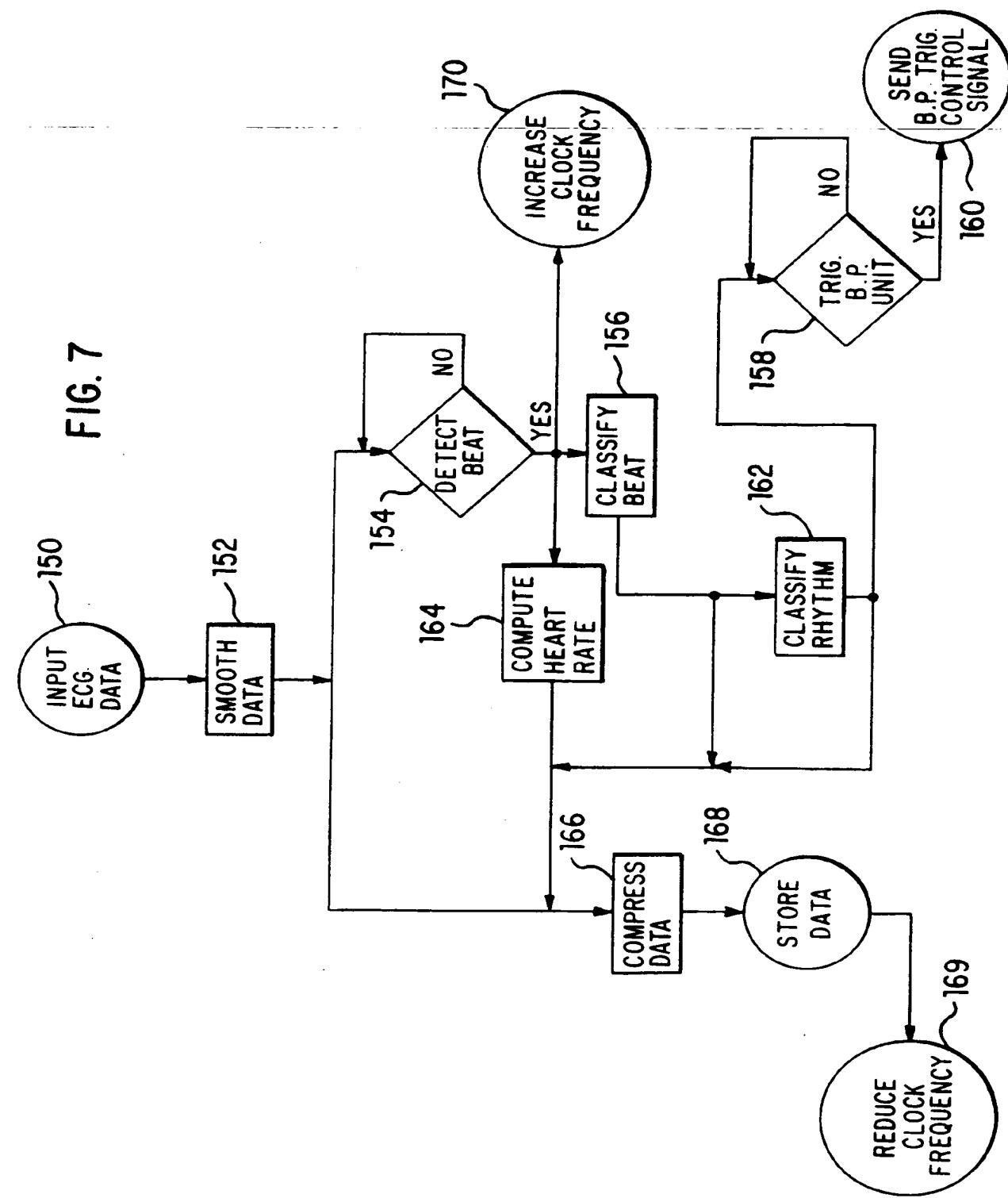
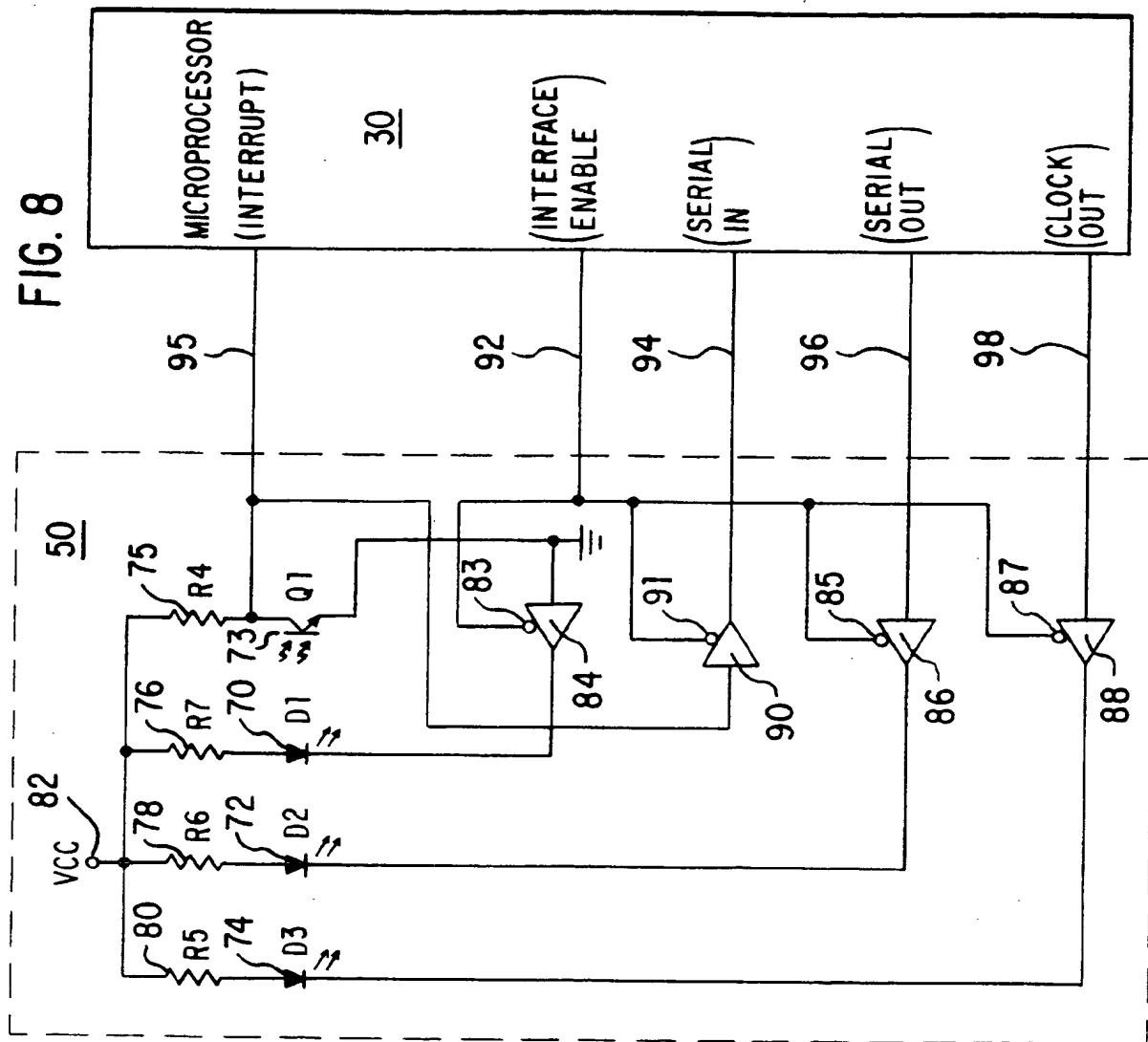


FIG. 8



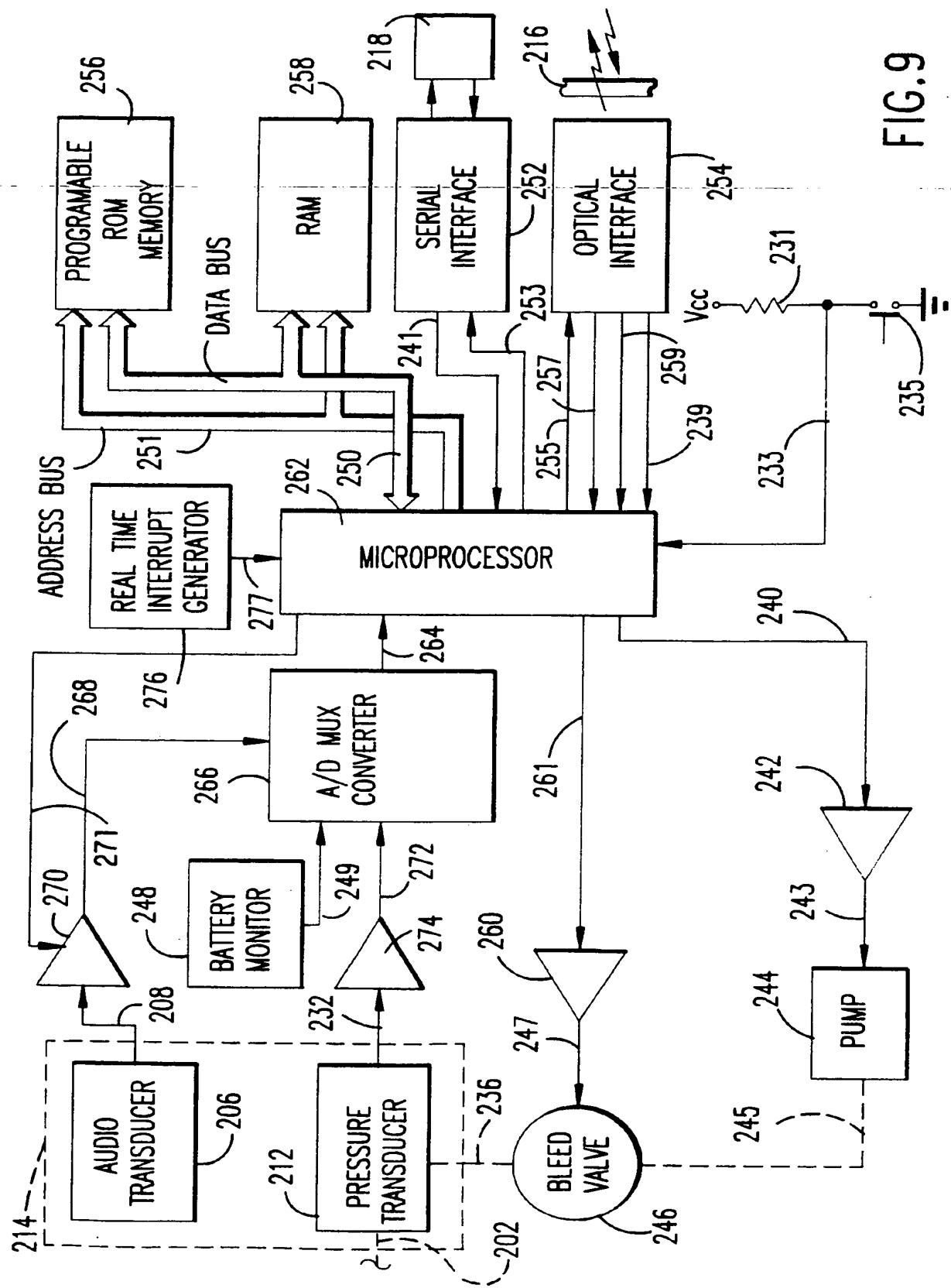


FIG. 9

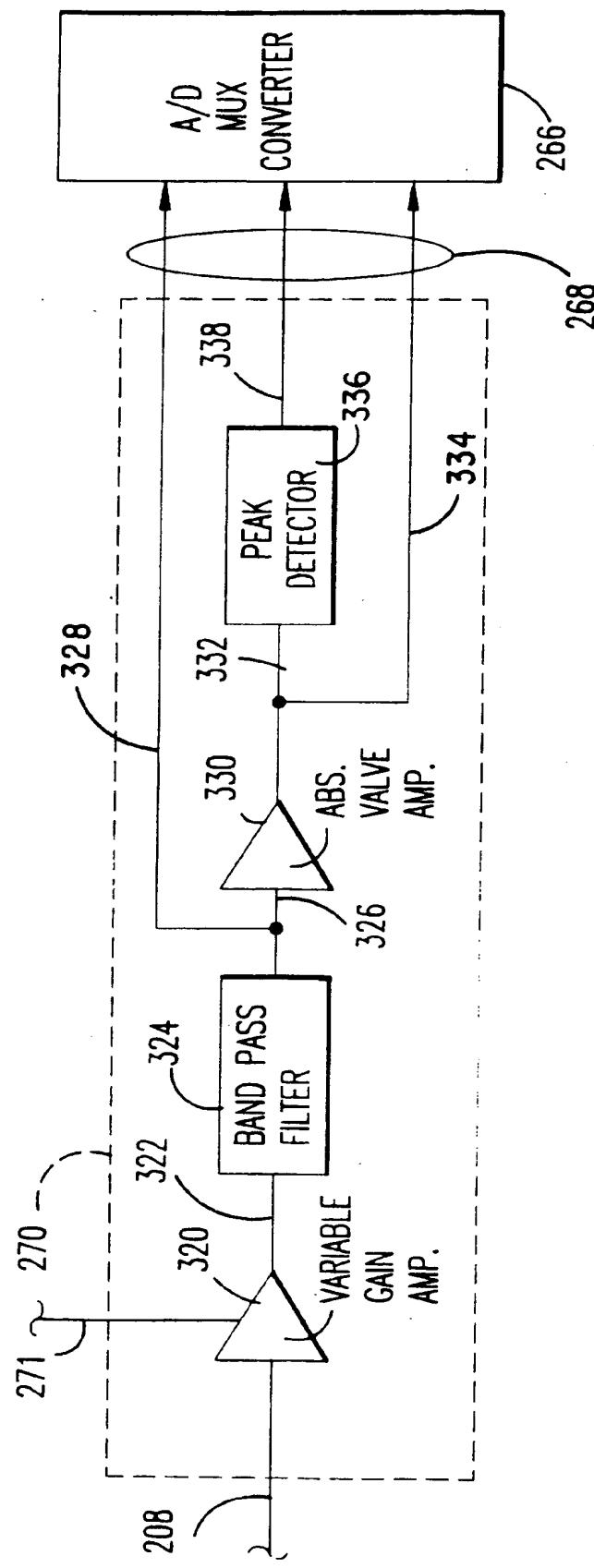


FIG.10

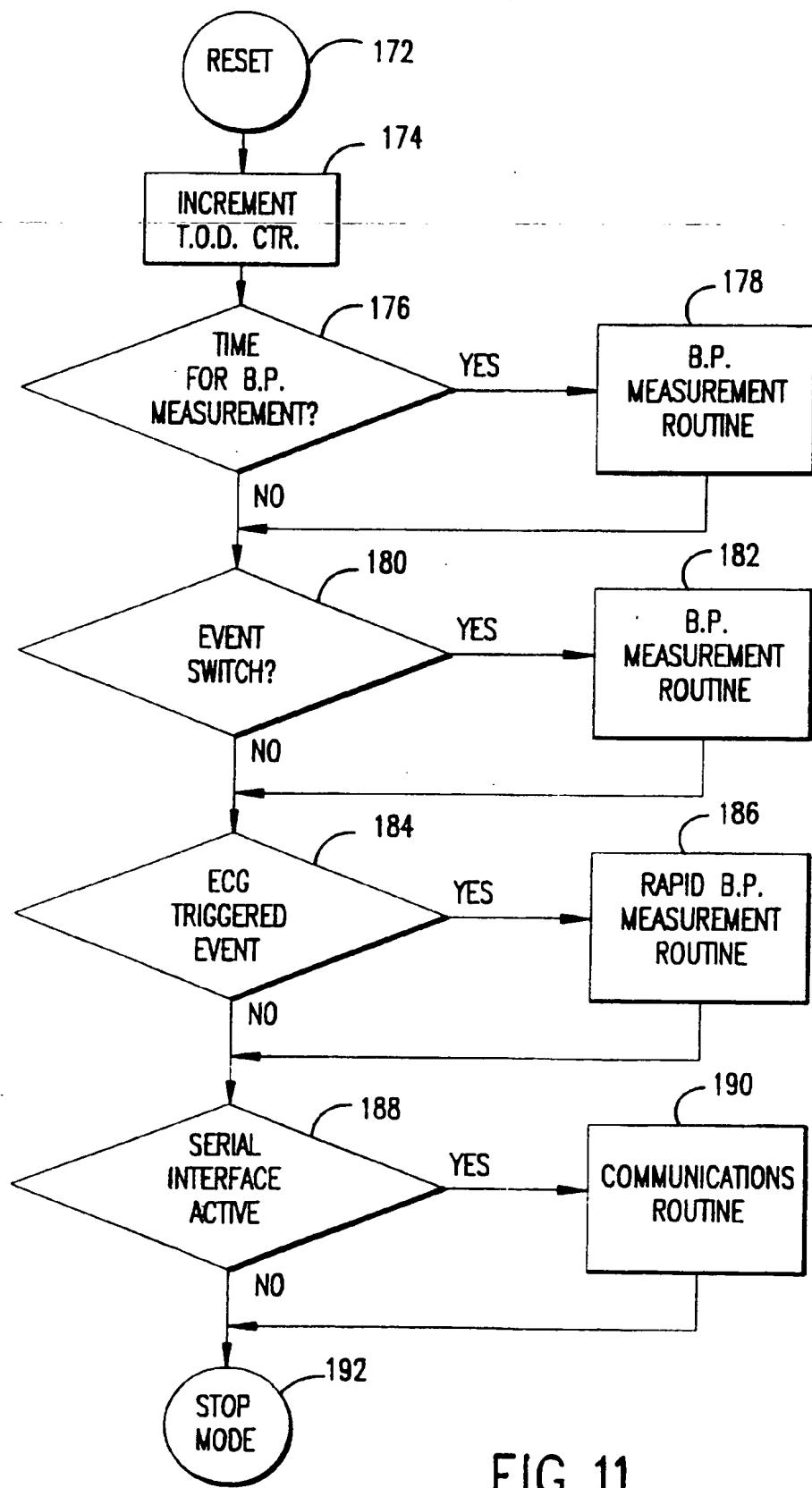


FIG. 11

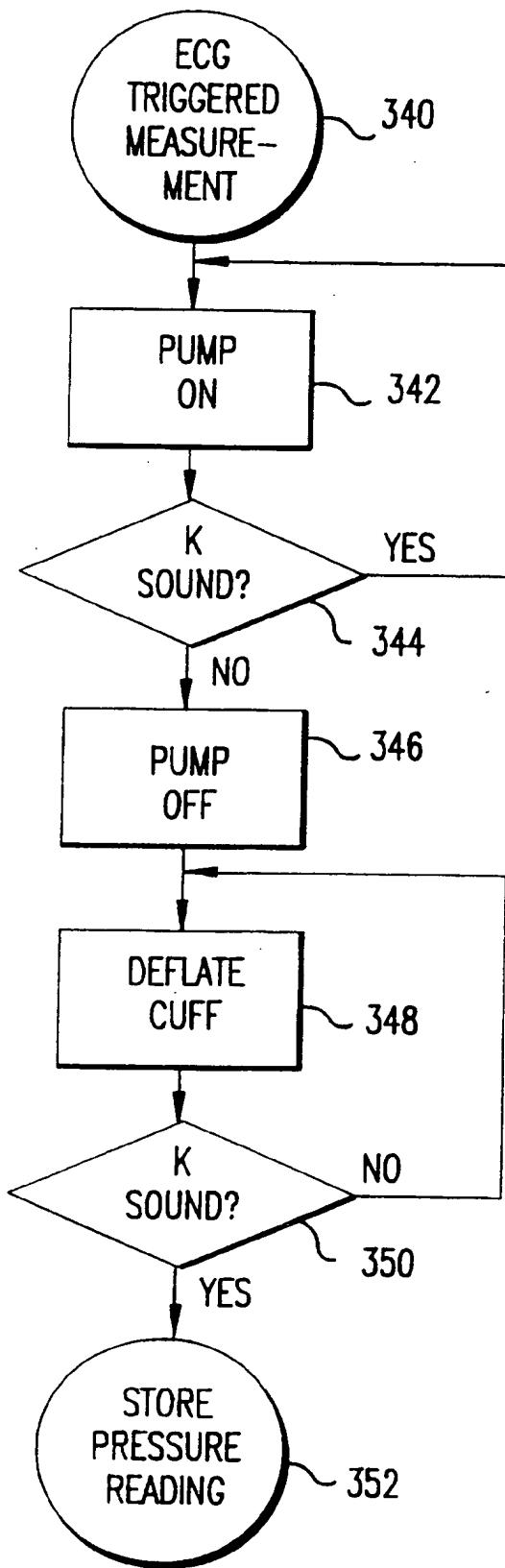


FIG.12



European Patent
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EUROPEAN SEARCH REPORT

Application Number

EP 92 30 8528

DOCUMENTS CONSIDERED TO BE RELEVANT			CLASSIFICATION OF THE APPLICATION (Int. Cl.5)		
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)		
X	GB-A-2 054 861 (DEL MAR AVIONICS) * page 1, line 107 - page 2, line 17 * * page 3, line 35 - page 7, line 2 * * figures 1-4,7 *	6,10	A61B5/0432 A61B5/0205 A61B5/022		
A	---	1,3,5,7, 9			
X	US-A-4 889 132 (HUTCHESON ET AL.) * column 6, line 59 - column 7, line 57 * * column 8, line 52 - column 16, line 5 * * column 17, line 35 - column 18, line 31 * * column 28, line 7 - line 21 * * figures 1-3 *	10			
A	---	1,3,5-8			
Y	WO-A-8 900 024 (MICROMEDICAL INDUSTRIES PTY LIMITED) * page 3, line 33 - page 9, line 33 * * figures 1-7 *	3,8			
A	---	1,4-7,9	TECHNICAL FIELDS SEARCHED (Int. Cl.5)		
Y	EP-A-0 445 809 (MÜLLER ET AL.) * column 1, line 1 - column 5, line 7 * * figure *	3,8			
A	---	1,5-7,9, 10	A61B		
A	WO-A-8 905 116 (AMERICAN HEALTH PRODUCTS, INC.) * page 8, line 8 - page 11, line 19 * * page 13, line 16 - page 18, line 19 * * figures 1-6,12,17 *	1,3,5-9			

The present search report has been drawn up for all claims					
Place of search	Date of completion of the search	Examiner			
THE HAGUE	25 FEBRUARY 1993	CHEN A.H.			
CATEGORY OF CITED DOCUMENTS					
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